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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,180	12/21/2001	Christian Meier	194070US0PCT	8287

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/600,180	Applicant(s) MEIER ET AL.	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment of 12/22/03 amended claims 1-10, and added new claims 11-21.

Claims examined on the merits are 1-21, which are all claims in
5 the application.

Kramer et al ('643) has been lined through on form PTO-1449 of 12/22/03 since the document was previously listed on form PTO-892.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C.
112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph,
20 because the specification, while being enabling for a support polymer having the binding capacity and swelling factor of claim 21 when the support polymer is a support polymer produced by the process of claim 1, does not reasonably provide enablement for another support polymer having the claimed binding capacity and swelling factor. The
25 specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The specification describes only a support polymer obtained by a process as required by claim 1 as having the claimed binding capacity and swelling factor. The specification contains no indication that another support polymer can have the claimed binding capacity and swelling factor, and contains no description of how to produce another support polymer. The specification in Examples 1-3 shows support polymers not having the claimed binding capacity and swelling factor produced by processes other than required by claim 1. The claims must be commensurate in scope with the specification.

Claim Rejections - 35 USC § 112

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, --- and --- should be inserted after the comma in line 4 of b) to be clear since claim 1 is requiring a), b) and c).

In line 2 of claim 15, "1.9 to 2.2" should be changed to --- 1:1.9 to 1:2.1 --- to be clear since the ratio of claim 15 further limits the ratio of claim 1 (last line) that recites "1:1.7 to 1:2.4".

Claim 19 is unclear by requiring covalently binding a ligand in line 1 and not requiring the subsequent step of contacting with a ligand to covalently bind the ligand. It is suggested that --- to covalently bind the ligand to the support polymer material --- be inserted between "ligand" and the comma in line 2.

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Dependent claim 20 is confusing by not having clear antecedent basis for "polymer beads" in line 1 since claim 19 on which claim 20 depends does not require producing polymer beads. It is suggested that "polymer beads" be replaced with --- support polymer material ---
5 , which is required in claim 19.

Claim Rejections - 35 USC § 102

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al (4,247,643).

The claim is drawn to a support polymer material having a binding
10 capacity for penicillin amidase from *E. coli* of at least 220 U/g moist, based on a reaction of 1530 units of penicillin amidase with 1 g of the support polymer material, and the support polymer material has a swelling factor of at most 1.5.

Kramer et al disclose (col 5, line 17) a support polymer
15 containing an activity of penicillin acylase (penicillin amidase) from *E. coli* of 237 U/g of moist product.

The support polymer of Kramer et al has a binding capacity for penicillin amidase as claimed since the activity of 237 U/g of moist product is at least 220 U/g as claimed. The claim requiring reacting
20 1530 units penicillin amidase with 1 g of support polymer material does not make the claimed support polymer material different from that of Kramer et al since support polymers having the same binding capacity for penicillin amidase are not made different by using different amounts of penicillin amidase in a process step of binding
25 the penicillin amidase to the support polymer. While the claim

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requires a swelling factor of at most 1.5, it appears the support polymer of Kramer et al will have this swelling factor since it has the same binding capacity for penicillin amidase per gram of moist support polymer as claimed.

5 ***Response to Arguments***

Applicants urge that the claimed support polymer is different from that of Kramer et al as shown by Example 1 according to the invention and comparison Examples 2 and 3 according to Kramer et al. However, comparative Examples 2 and 3 resulted in a binding capacity
10 of 194 and 192 U/g moist product, respectively, which is substantially lower than the 237 U/g moist product obtained by Kramer et al. Apparently, the comparison examples did not produce the support polymer precisely as disclosed by Kramer et al ('643). This difference in preparing the support polymer from Kramer et al
15 apparently resulted in a greater swelling factor of 4.0 and 3.9 for the comparison examples. The higher binding capacity of 237 U/g obtained by Kramer et al relative to the comparison examples would have inherently resulted in a swelling factor of 1.5 or less.

Applicants urge that in contrast to Kramer et al, the use of
20 halogenated solvents can be avoided by the present invention. However, the claim does not exclude the use of halogenated solvents, and the method of Kramer et al can be used to make the support polymer of the claim.

Claims 1-20 are free of the prior art.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

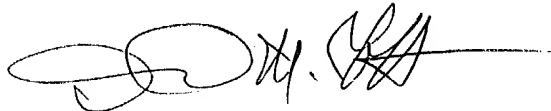
5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the
10 shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX
MONTHS from the date of this final action.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
20 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
3/17/04